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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,525	02/05/2002	Karla Robotti	10011206	2898
22878	7590	11/04/2003	EXAMINER	
AGILENT TECHNOLOGIES, INC. INTELLECTUAL PROPERTY ADMINISTRATION, LEGAL DEPT. P.O. BOX 7599 M/S DL429 LOVELAND, CO 80537-0599			NGUYEN, QUANG	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/072,525	Applicant(s) ROBOTTI, KARLA	
	Examiner Quang Nguyen, Ph.D.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-59 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-59 are pending in the present application, and they are subjected to the following restrictions.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group Restrictions

- I. Claims 1-56 and 58-59, drawn to a method for immobilizing a biological molecule in a porous inorganic matrix, a method for preparing a microanalytical device comprising the same entrapped or immobilized biological molecule, and a method of using the same microanalytical device, wherein the biological molecule is a polynucleotide, a gene, or a gene fragment, classified in class 435, subclass 6; class 436, subclass 527.
- II. Claims 1-56 and 58-59, drawn to a method for immobilizing a biological molecule in a porous inorganic matrix, a method for preparing a microanalytical device comprising the same entrapped biological molecule, and a method of using the same microanalytical device, wherein the biological molecule is an enzyme or an antibody or a coagulation modulator or a cytokine or an endorphin or a peptidyl hormone or a kinin or a receptor or a solubilized membrane protein, classified in class 435, subclasses 4, 7.1; class 436, subclass 527, for examples.

- III. Claims 1-56 and 58-59, drawn to a method for immobilizing a biological molecule in a porous inorganic matrix, a method for preparing a microanalytical device comprising the same entrapped biological molecule, and a method of using the same microanalytical device, wherein the biological molecule is a cell membrane or a membrane fragment, classified in class 435, subclass 7.2; class 436, subclass 527.
- IV. Claims 57 and 59, drawn to a microanalytical device comprised of a substrate and at least one feature particulates of sol-gel having a diameter of from about 10 μm to about 80 μm , classified in class 436, subclass 527.

Claims 1-41, 43-56 and 58-59 link patentably distinct inventions of Groups I to III that lack unity of invention. This is because a biological molecule entrapped in a porous inorganic matrix comprises nucleic acids (e.g., a polynucleotide, a gene, or a gene fragment), proteins (e.g., an enzyme or an antibody or a coagulation modulator or a cytokine or an endorphin or a peptidyl hormone or a kinin or a receptor or a solubilized membrane protein) and cell fragments or membrane fragments that are distinct in chemical compositions having different biological activities, and the methods for entrapping these biological molecules and for utilizing these distinct compositions require different technical considerations for achieving the desired end-results. It is noted that the activity of the immobilized or entrapped biological material is sensitive to the preparation and conditions employed during the use of the sol-gel. Since the operation, function and effects of these different methods are different and distinct one from the other, the inventions of these different, distinct groups are capable of

supporting separate patents. Additionally, as set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-132 (CCPA 1971). See also MPEP 804.01.

The above inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I to III are distinct methods involving different starting biological materials being immobilized or entrapped within a porous inorganic matrix and that they require different technical considerations for achieving the desired end-results. The microanalytical device of Group IV is distinct from any of the microanalytical devices of Groups I to III because it does not contain any biological material being immobilized or entrapped within a sol-gel or a porous inorganic matrix.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and separate search requirements, it would be unduly burdensome for the examiner to search and/or consider the patentability of all the inventions in a single application. Therefore, restriction for examination purposes as indicated is proper.

Species Restriction

Should Applicant elects Group II, claims 1 and 41 comprise the following patentably distinct species:

(a) enzymes, (b) antibodies, (c) coagulation modulators, (d) cytokines, (e) endorphins, (f) peptidyl hormones, (g) kinins, (h) receptors and (i) solubilized membrane proteins.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Additionally, should Applicant elects the species (a) above, claims 1, 41-42 comprise the following patentably distinct species:

A specific enzyme species recited in the Markush group of claim 42.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

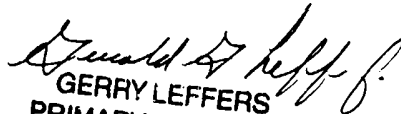
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Gerald Leffers, Jr., Ph.D., may be reached at (703) 305-6232, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Quang Nguyen, Ph.D.


GERY LEFFERS
PRIMARY EXAMINER